CLAIMS

What is claimed is:

1. An aqueous solution comprising a therapeutically effective concentration of prednisolone or a water-insoluble prodrug thereof and a water-soluble cyclodextrin derivative.

2. The solution of claim 1 comprising a β-cyclodextrin derivative.

3. The solution of claim 1 comprising a β-cyclodextrin derivative and a water-soluble polymer.

4. The solution of claim 1 comprising prednisolone acetate, hydroxypropyl-β-cyclodextrin, and hydroxypropylmethylcellulose.

5. The solution of claim 1 comprising a γ-cyclodextrin derivative.

6. The solution of claim 5 comprising prednisolone acetate.

7. The solution of claim 5 wherein said cyclodextrin derivate is hydroxypropyl-γ-cyclodextrin.

8. The solution of claim 5 which further comprises a cellulose derivative.

9. The solution of claim 5 which further comprises hydroxypropylmethylcellulose having a concentration less than 1%.

10. The solution of claim 5 comprising from 0.05% to 0.4% hydroxypropylmethylcellulose.

11. The solution of claim 5 comprising about from 0.1% to 0.25% hydroxypropylmethylcellulose.

12. The composition of claim 5 comprising from 0.6% to 1.6% prednisolone acetate, from 10% to 25% hydroxypropyl-γ-cyclodextrin, from 0% to 0.15% hydroxypropylmethylcellulose, a buffer, and a chelating agent, wherein said composition is isotonically adjusted for ophthalmic administration, and said composition has a pH of from 4.5 to 5.5.

13. An aqueous liquid comprising a therapeutically effective concentration of prednisolone acetate and a water-soluble cyclodextrin derivative, wherein prednisolone acetate is dissolved in said liquid and wherein said liquid is suitable for ophthalmic administration.

14. The liquid of claim 13 comprising a β-cyclodextrin derivative.

15. The liquid of claim 13 comprising hydroxypropyl-β-cyclodextrin and β-hydroxypropylmethylcellulose.

16. The liquid of claim 13 comprising a γ-cyclodextrin derivative.

17. The liquid of claim 13 wherein said cyclodextrin derivative has an osmolality of less than 300 mOsm/kg at a concentration of 12% w/v.

18. The liquid of claim 13 wherein said cyclodextrin derivative has an osmolality of less than 300 mOsm/kg at a concentration of 25% w/v.

19. The liquid of claim 16 wherein said cyclodextrin derivative is hydroxypropyl-γ-cyclodextrin.

20. The liquid of claim 16 comprising less than 1% hydroxypropylmethylcellulose.

21. The liquid of claim 16 comprising about from 0.12% to 0.3% hydroxypropylmethylcellulose.

22. The liquid of claim 13 comprising from 0.6% to 1.6% prednisolone acetate, from 10% to 25% hydroxypropyl-γ-cyclodextrin, from 0% to 0.15% hydroxypropylmethylcellulose, a buffer, and a chelating agent, wherein said composition is isotonically adjusted for ophthalmic administration, and said composition has a pH of from 4.5 to 5.5.

23. A pharmaceutical product comprising

a solution comprising a therapeutically effective concentration of a nonionic prednisolone prodrug and a water-soluble cyclodextrin derivative, wherein said solution has an ophthalmically acceptable pH, and

a container suitable for dispensing drops of said solution to the eye of a mammal in need of treatment by said prodrug.

24. The product of claim 23 comprising prednisolone acetate.

25. The product of claim 23 comprising hydroxypropylmethylcellulose.

26. The liquid of claim 13 comprising about 1.2% prednisolone acetate, about 25% hydroxypropyl-γ-cyclodextrin, about 0.12% hydroxpropylmethylcellulose, an effective amount of a preservative, an effective amount of a chelating agent, and an effective amount of NaCl to make said liquid isotonic, and wherein the pH of said solution is about 4.8.

27. The liquid of claim 13 comprising about 0.6% prednisolone acetate, about 15% hydroxypropyl-γ-cyclodextrin, about 0.12% hydroxpropylmethylcellulose, an effective amount of a preservative, an effective amount of a chelating agent, and an effective amount of NaCl to make said liquid isotonic, and wherein the pH of said solution is about 4.8.

28. The liquid of claim 13 comprising about 0.6% prednisolone acetate, about 25% hydroxypropyl-γ-cyclodextrin, an effective amount of a preservative, an effective amount of a chelating agent, and an effective amount of NaCl to make said liquid isotonic, and wherein the pH of said solution is about 4.8.

29. The liquid of claim 13 comprising about 1% prednisolone acetate, about 25% hydroxypropyl-γ-cyclodextrin, an effective amount of a preservative, an effective amount of a chelating agent, and an effective amount of NaCl to make said liquid isotonic, and wherein the pH of said solution is about 4.8.

30. The liquid of claim 13 comprising about 1% prednisolone acetate, about 25% hydroxypropyl-γ-cyclodextrin, about 0.12% hydroxpropylmethylcellulose, an effective amount of a preservative, an effective amount of a chelating agent, and an effective amount of NaCl to make said liquid isotonic, and wherein the pH of said solution is about 4.8.

31. The liquid of claim 13 comprising about 1.2% prednisolone acetate, about 30% hydroxypropyl-β-cyclodextrin, about 0.5% hydroxpropylmethylcellulose, an effective amount of a preservative, and an effective amount of NaCl to make said liquid isotonic, and wherein the pH of said solution is about 4.8.

32. The liquid of claim 13 comprising about 0.5% prednisolone acetate, about 10% of a cyclodextrin derivative, and about 0.5% hydroxypropylmethylcellulose.

33. The solution of claim 1 wherein the concentration of the cyclodextrin or cyclodextrin derivative is greater than 10% and the concentration of prednisolone or the water-soluble prodrug thereof is greater than 0.5%.

34. The liquid of claim 13 wherein the concentration of the cyclodextrin derivative is greater than 10%.

35. The liquid of claim 13 wherein the concentration of prednisolone acetate is greater than 0.5%.

36. The liquid of claim 13 comprising about 0.4% prednisolone acetate, about 10% hydroxypropyl-β-cyclodextrin, and about 0.5% hydroxypropylmethylcellulose.

37. The liquid of claim 13 comprising
from 0.1% to 1.5% prednisolone acetate,
from 5% to 35% hydroxypropyl-β-cyclodextrin or hydroxypropyl-γ-cyclodextrin, and
from 0% to 1% hydroxypropylmethylcellulose.

38. A method comprising administering a solution comprising prednisolone acetate and a cyclodextrin derivative to a mammal suffering from a disease or condition affecting the eye of said mammal wherein said disease or condition is selected from the group consisting of maculopathies, retinal degeneration, uveitis, retinitis, choroiditis, vascular diseases, exudative diseases, conditions related to traumatic or surgery, proliferative disorders, infectious disorders, genetic disorders, retinal tears and/or holes, retinal tumor, punctate inner choroidopathy, acute posterior multifocal placoid pigment epitheliopathy, myopic retinal degeneration, and acute retinal pigment epithelitis.

39. A method comprising
topically administering to an eye of a mammal
prednisolone, a water-insoluble prodrug of prednisolone, or a combination thereof, and
a cyclodextrin derivative,
wherein prednisolone, or the water-insoluble prodrug, or a combination thereof, is delivered to the back of said eye of said mammal.

40. The method of claim 39 wherein a solution comprising prednisolone acetate and hydroxpropyl-β-cyclodextrin is administered.

41. The method of claim 39 wherein a solution comprising prednisolone acetate and hydroxypropyl-γ-cyclodextrin is administered.

42. The solution of claim 39 which further comprises a cellulose derivative.

43. The solution of claim 39 which further comprises hydroxypropylmethylcellulose having a concentration less than 1%.

44. The solution of claim 39 comprising from 0.05% to 0.4% hydroxypropylmethylcellulose.

45. The solution of claim 39 comprising about from 0.1% to 0.25% hydroxypropylmethylcellulose.

46. A composition comprising prednisolone or a water-insoluble prodrug thereof and a cyclodextrin derivative, wherein said composition is soluble in water in an amount such that the concentration of prednisolone or the water-insoluble prodrug thereof is therapeutically effective.